

Claims:

1. An apparatus for the delivery of an electrical field which facilitates the intracellular delivery of a therapeutic agent to a predetermined site within the tissue of a patient comprising:

a) a plurality of penetrating electrodes arranged in a predetermined spatial relationship, each electrode with a cross sectional area contributing to the total cross sectional area of all electrodes;

b) structural means incorporating an inanimate source of energy operatively connected to said plurality of electrodes for deploying said electrodes, and wherein said source of energy is sufficient to impart a force of at least 1000 pounds per square inch (0.7kg/square millimeter) of total cross sectional area of all electrodes at the initiation of the deployment of said electrodes; and

c) means for generating an electrical field which facilitates the intracellular delivery of a therapeutic agent, which means is operatively connected to said electrodes at least in their deployed state.

2. An apparatus for the intracellular delivery of a therapeutic agent to a predetermined site within the tissue of a patient comprising:

a) a plurality of penetrating electrodes arranged in a predetermined spatial relationship, each electrode with a cross sectional area contributing to the total cross sectional area of all electrodes;

b) structural means incorporating an inanimate source of energy operatively connected to said plurality of electrodes for deploying said electrodes, and wherein said source of energy is sufficient to impart a force of at least 1000 pounds per square inch (0.7kg/square millimeter) of total cross sectional area of all electrodes at the initiation of the deployment of said electrodes;

c) structural means configured to accept a fluid reservoir for containing a therapeutic agent said reservoir operatively connected to at least one injection orifice;

d) actuation means configured to transmit said therapeutic agent through said orifice to the predetermined site within the tissue of the patient; and

e) means for generating an electrical field which facilitates the intracellular delivery of said therapeutic agent, which means is operatively connected to said electrodes at least in their deployed state.

5 3. The apparatus as recited in claims 1 or 2 wherein the source of energy to deploy the electrodes is at least one spring.

 4. The apparatus as recited in claims 1 or 2 wherein the source of energy to deploy the electrodes is at least one compressed gas.

10 5. The apparatus as recited in claims 1 or 2 wherein the source of energy to deploy the electrodes is a linear motor.

 6. The apparatus as recited in claims 1 or 2 wherein the electrodes comprise a
15 subassembly that can be separated from the source of energy.

 7. The apparatus as recited in claim 2 wherein the reservoir and orifice comprise a needle and syringe.

20 8. The apparatus as recited in claim 7 wherein the syringe is provided pre-filled with the therapeutic agent.

 9. The apparatus as recited in claim 2 wherein the reservoir comprises a glass vial.

25 10. The apparatus as recited in claim 2 wherein the reservoir and orifice comprise a subassembly that can be separated from the source of energy.

 11. The apparatus as recited in claim 2 wherein the electrodes, reservoir, and orifice are housed within a single subassembly that can be separated from the source of energy.

30 12. The apparatus of claim 11 wherein the reservoir is provided pre-filled with the therapeutic agent.

13. The apparatus as recited in claims 1 or 2 wherein the electrodes comprise a conductive metal coated with a conductive, electrochemically stable compound.

5 14. The apparatus as recited in claims 1 or 2 wherein said conductive, electrochemically stable compound is selected from the group consisting of: titanium nitride, platinum, platinum iridium alloys, and iridium oxide.

10 15. The apparatus as recited in claims 1 or 2 wherein the means for generating an electrical field is configured to induce an electrical field of from approximately 50 to approximately 300 V/cm between at least two of said electrodes.

15 16. The apparatus as recited in claims 1 or 2 wherein the means for generating an electrical field is configured to deliver said field for a duration of from approximately 1 microsecond to approximately 100 milliseconds and at a frequency of from approximately 0.1 Hertz to approximately 1 megahertz to at least two of said electrodes.

17. An apparatus for the intracellular delivery of a therapeutic agent to a predetermined site within the tissue of a patient comprising:

20 a) fluid reservoir for containing a therapeutic agent, said reservoir operatively connected to at least one injection orifice;

b) actuation means configured to transmit said therapeutic agent through said orifice to the predetermined site within the tissue of the patient;

25 c) a plurality of penetrating electrodes arranged in a predetermined spatial relationship;

d) structural means incorporating operative connections for said penetrating electrodes, said fluid reservoir, and said injection orifice wherein said structural means is configured to allow disposition of said plurality of electrodes and said injection orifice within the tissue of a patient according to a predetermined spatial relationship;

30 e) an inanimate source of energy operatively connected to said actuation means wherein said source of energy is configured to apply a force of at least 0.25 pounds (1.1 Newtons) through said fluid reservoir to said therapeutic agent; and

f) means for generating an electrical field which facilitates the intracellular delivery of said therapeutic agent, which means is operatively connected to said electrodes at least in their deployed state.

5 18. The apparatus as recited in claim 17 wherein the source of energy to transfer the therapeutic agent from the reservoir through the orifice is at least one spring.

 19. The apparatus as recited in claim 17 wherein the source of energy to transfer the therapeutic agent from the reservoir through the orifice is at least one compressed gas.

10 20. The apparatus as recited in claim 17 wherein the source of energy to transfer the therapeutic agent from the reservoir through the orifice is a linear motor.

 21. The apparatus as recited in claim 17 wherein the reservoir and orifice comprise a
15 syringe and hypodermic needle.

 22. The apparatus as recited in claim 21 wherein the syringe is provided pre-filled with the therapeutic agent.

20 23. The apparatus as recited in claim 17 wherein the reservoir is a glass vial.

 24. The apparatus as recited in claim 17 wherein the electrodes comprise a subassembly that can be separated from the inanimate source of energy.

25 25. The apparatus as recited in claim 17 wherein the reservoir and orifice comprise a subassembly that can be separated from the inanimate source of energy.

 26. The apparatus as recited in claim 17 wherein the electrodes, reservoir, and orifice are housed within a single subassembly that can be separated from the inanimate source of
30 energy.

27. The apparatus as recited in claim 17 wherein the electrodes comprise a conductive metal coated with a conductive, electrochemically stable compound.

28. The apparatus as recited in claim 17 wherein said conductive, electrochemically
5 stable compound is at least one material selected from the group consisting of: titanium nitride, platinum, platinum iridium alloys, and iridium oxide.

29. The apparatus as recited in claim 17 wherein the means for generating an
electrical field is configured to induce an electrical field of from approximately 50 to
10 approximately 300 V/cm between at least two of said electrodes.

30. The apparatus as recited in claim 17 wherein the means for generating an
electrical field is configured to deliver said field for a duration of from approximately 1
microsecond to approximately 100 milliseconds and at a frequency of from approximately 0.1
15 Hertz to approximately 1 megahertz to at least two of said electrodes.